

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Williams et al.

Serial No.: 08/547,766

COPY

Filed: October 24, 1995

For: SOFT, FLEXIBLE COMPOSITION AND METHOD
FOR MAKING SAME

Examiner: Mark Warzel

Group: 1511

Attorney Docket No.: 460.1815USU

BOX AF
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231**DECLARATION**

Dear Sir:

1. I, Karla E. Williams, hereby declare and state as follows:

2. I am a citizen of the United States, and reside at 102
Munsey Road, Emerson, New Jersey, 07630.3. I have been employed at Playtex Products, Inc. continuously
since September 1982 in the field of Feminine Care Research and
Development. My current position is Senior Group Leader.4. I am the co-inventor of the subject matter of the above-
identified patent application. I am familiar with the manner in

which the comparative tests of the present application were conducted.

5. The comparative tests compared known branded thermoplastic applicator barrels to applicator barrels of the preferred composition of the present invention. The test results are set forth in the application at Table B on page 18. The test of the above-mentioned applicator barrels was conducted on an Instron testing device, model no. 1122. The Instron device has computer software (Software series 9, Version 6.05) that calculates the Young's modulus of elasticity from data compiled during each test run. The software has various options for method of calculation. Unfortunately, the calculation method used, 19.3, was an "automatic calculation method" in which some dimensions are entered automatically. This method required that the diameter of the tampon applicator barrels be entered. While the calculation method called for "gauge length", which is a second entry of the barrel's diameter, it was assumed that this "automatic calculation method" automatically inserted the proper "gauge length", namely the barrel diameter. Instead, however, the "gauge length" defaulted to a constant of 0.187 inches. A "manual calculation method", 18.3, should have been used. This method required that the barrel diameter be entered both as the "diameter" and as the "gauge length."

6. The default gauge length was used to calculate the Young's modulus of each tampon applicator barrels tested, including the known branded tampon applicator barrels and the tampon applicator barrels of the present invention. Since the actual diameters of the tested tampon applicator barrels varied between about 0.50 inches to about 0.74 inches, each Young's modulus calculated by the Instron Device was approximately one-third of the actual Young's modulus for that tampon applicator barrel.

7. Thus, the ratio of Young's modulus for the preferred composition applicator barrels to the Young's modulus for the known branded applicator barrels was as expected. Accordingly, the accuracy of the actual numbers calculated was assumed correct. In late 1997, the Young's modulus results were evaluated to confirm test results for another project. At that time, it was discovered there existed a discrepancy between the Young's modulus numbers set forth in the present application and those derived for the second project. However, the source of the discrepancy was unknown.

8. Various possible sources for the discrepancy were evaluated. Accordingly, the manufacturer of the Instron testing device was contacted. The manufacturer was not able to locate the source of the inaccuracies until about November 1997. In December 1997, it became evident that the Young's modulus data submitted in the application was affected, but it was not known what was the

correct data. In January 1998, the corrected Young's modulus data was generated.

9. The corrected Young's modulus may be obtained by using the following conversion equation:

$$\frac{\text{Corrected Young's Modulus}}{0.187} \times \text{Gauge Length (Diameter of Applicator Barrel)}$$

10. Thus, Table B, as corrected, should read as follows:

TABLE B: Instron Compression Testing

Tampon applicator barrels having an outside diameter about 0.67 inches +/- .07 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	2.22 to 3.59 (0.16)	191.9 to 277.5 (20.4)	0.28 to 0.46 (0.02) (0.03)
Preferred Composition Applicator	1.74 (0.10)	104.2 (11.8)	0.22 (0.01)

Tampon applicator barrels having an outside diameter about 0.56 inches +/- .06 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	3.11 to 4.85 (0.28)	239.4 to 474.8 (26.6)	0.40 to 0.62 (0.04) (0.05)
Preferred Composition Applicator	1.96 (0.20)	113.0 (17.6)	0.25 (0.03)

11. This corrected data supports the present invention. The corrected Young's modulus for the applicator barrel of the present invention having a diameter about 0.56 inches is about 113.0, which is at least one-half of the corrected Young's modulus values obtained for the known branded applicator barrels having approximately the same diameter. The corrected Young's modulus for the applicator barrel of the present invention having a diameter of about 0.67 inches is about 104.2, which is also about one-half of the corrected Young's modulus values obtained for the known-branded applicator barrels having approximately the same diameter. This ratio of corrected Young's modulus for applicator barrels of the present invention to corrected Young's modulus for known branded applicator barrels is consistent with the ratio of the corresponding uncorrected Young's modulus set forth in original Table B of the application.

12. Young's modulus is a constant value for any specific material having a certain size. The composition of the preferred composition applicator barrel is set forth in the application at page 15, Table A, and at page 22, as composition D in Table C. Therefore, any one making such a preferred composition applicator barrel, and then measuring the preferred composition applicator barrel for Young's modulus, would obtain the corrected Young's modulus values as set forth herein.

I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Karen E. Williams

Karla E. Williams

Dated: March 9, 1998